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**IN THE UNITED STATES DISTRICT COURT**  
**FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability  
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS C. R. BARD, INC.'S  
AND BARD PERIPHERAL  
VASCULAR, INC.'S REPLY IN  
SUPPORT OF ITS MOTION TO  
AMEND AND CERTIFY THE  
COURT'S NOVEMBER 22, 2017  
ORDER FOR INTERLOCUTORY  
APPEAL PURSUANT TO 28 U.S.C.  
§ 1292(B)**

(Assigned to the Honorable David G.  
Campbell)

The Court's November 22, 2017, Summary Judgment Order involves pure and controlling questions of law, involving novel legal issues on which fair-minded jurists might reach contradictory conclusions, and an immediate appeal, if successful, will materially advance the ultimate termination of this litigation. 28 U.S.C. § 1292(b).

Certification is especially appropriate given the MDL setting. For each of these reasons, and as discussed in Bard’s Motion, certification is appropriate:

**I. The Order Involves “Pure Questions of Law” Appropriate for Interlocutory Review.**

“A ‘question of law’ for purposes of § 1292(b) means a ‘pure question of law’ rather than a mixed question of law and fact or the application of established law to a particular set of facts.” *BDPJ Houston, LLC v. Cont’l Cas. Co.*, No. 2:10-CV-01018-TMB, 2012 WL 13018736, at \*2 (D. Ariz. Dec. 27, 2012). “So long as a pure legal question is identified, however, an order can be certified for appeal to resolve all questions ‘material to the order.’” *Steering Comm. v. United States*, 6 F.3d 572, 575 (9th Cir. 1993) (finding it proper to certify a mixed question of law and fact material to the order when it is coupled with a pure legal question). *TCL Commc’ns Tech. Holdings Ltd v. Telefonaktenbologet LM Ericsson*, No. SACV1400341JVSANX, 2014 WL 12588293, at \*3 (C.D. Cal. Sept. 30, 2014); *Flores v. Velocity Express, LLC*, No. 12-CV-05790-JST, 2015 WL 4463639, at \*3 (N.D. Cal. July 21, 2015) (“[T]his prong is satisfied because at least one ‘pure’ question of law is presented.”). Bard acknowledges that the Order involves some mixed questions of law and fact. But these questions “are material to the order” and can be resolved alongside the multiple “pure questions of law” also presented for certification.

**A. Whether Plaintiffs’ State Law Claims Are Impliedly Preempted Is a Purely Legal Question.**

Federal preemption under the FDCA is a “purely legal” question. *Delarosa v. Boiron, Inc.*, No. 10-1569-JST (CWX), 2011 WL 13130856, at \*4 (C.D. Cal. Dec. 29, 2011). It is “undoubtedly a controlling question of law.” *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 599 (E.D. Pa. 2008). As here, the plaintiff in *Knipe* argued “that the issue of preemption is fact-intensive and, thus, not a pure question of law. . . . This argument disregards the very nature of the conflict preemption analysis, which turns precisely on whether two laws or regulations—one state, one federal—conflict, such that

the latter preempts the former.” *Id.* “The mere fact that the preemption issue may require a detailed review of the regulatory records does not deprive it of its dispositive nature.” *Id.*

As in *Knipe*, the Ninth Circuit and its district courts have repeatedly recognized that preemption, by its very nature, is a controlling question of law. *E.g.*, *Movsesian v. Victoria Versicherung AG*, 578 F.3d 1052, 1053 (9th Cir. 2009); *Harris By & Through Harris v. Ford Motor Co.*, 110 F.3d 1410, 1411-12 (9th Cir. 1997); *TOTAL TV v. Palmer Commc’ns, Inc.*, 69 F. 3d 298, 300–01 (9th Cir. 1995) (hearing interlocutory appeal of denial of federal preemption defense that presented an issue of first impression in the Circuit); *Delarosa*, 2011 WL 13130856, at \*4 (“[W]hether the FDCA expressly or impliedly preempts each of Plaintiff’s state law claims” is controlling question of law); *Hansen Beverage Co. v. Innovation Ventures, LLC.*, No. 08CV1166 IEG(POR), 2010 WL 743750, at \*2 (S.D. Cal. Feb. 25, 2010) (“Hansen satisfies the first criterion for interlocutory appeal because federal preemption [under the FDCA] is a controlling issue of law.”); *see also Nutrishare, Inc. v. Connecticut Gen. Life Ins. Co.*, No. 2:13-CV-02378-JAM-AC, 2014 WL 2624981, at \*4 (E.D. Cal. June 12, 2014) (granting certification; finding federal preemption “certainly a controlling question of law”); *Brown v. Hain Celestial Grp., Inc.*, No. C 11-03082 LB, 2012 WL 4364588, at \*3 (N.D. Cal. Sept. 24, 2012) (granting certification; federal “preemption question presents a controlling question of law”); *Deming v. First Franklin*, No. 09-5418RJB, 2010 WL 2326170, at \*1 (W.D. Wash. June 7, 2010) (whether federal statute and regulations preempted plaintiff’s state common law claims was a question of law); *Helman v. Alcoa Glob. Fasteners Inc.*, No. CV09-1353 SVW (FFMX), 2009 WL 2058541, at \*5 (C.D. Cal. June 16, 2009) (preemption is a “pure legal question”).<sup>1</sup>

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<sup>1</sup> Other district courts have similarly found federal preemption under the FDCA to be a controlling question of law. *E.g.*, *Huber v. Howmedica Osteonics Corp.*, No. CIV A 07-2400 JLL, 2009 WL 2998160, at \*2 (D.N.J. Mar. 10, 2009) (granting certification in medical device case; “whether the MDA preempts a claim for breach of express warranty is a ‘controlling question of law.’ . . . As such, there is no question that the first 1292(b) factor is satisfied.”); *Shuker v. Smith & Nephew PLC*, No. CIV.A. 13-6158, 2015 WL 4770987, at \*4 (E.D. Pa. Aug. 13, 2015) (“[P]reemption ruling presents controlling questions of law, including whether the MDA preempts state tort claims concerning the

**B. Whether Special Controls, Such as a FDA Guidance Document, Can Ever Impose Device-Specific Requirements With Preemptive Power Is a Pure Legal Question.**

Whether special controls and/or FDA Guidance documents can “ever” bear preemptive power is a “purely legal question.” *Flores*, 2015 WL 4463639, at \*2 (“[W]hether successor liability *ever* applies . . . is a question of law. The question of whether it applies to *this particular acquisition* is a mixed question of law and fact.”); This question requires interpretation of the legal import of 21 C.F.R. § 870.3375, and FDA’s Filter Guidance, within the Supreme Court’s preemption jurisprudence, not “the parties’ factual circumstances.” *Nat’l Credit Union Admin. Bd. v. Goldman Sachs & Co.*, No. CV 11-6521-GW(JEMX), 2013 WL 12306438, at \*6 (C.D. Cal. July 11, 2013) (question is “purely legal” where “order merely deals with a question of statutory interpretation” and “appellate court need not address the parties’ factual circumstances.”).

**C. Whether the Statutory and Regulatory Framework of 510(k) Has Evolved With The Passage of the SMDA Such That 510(k) Review Can Ever Impose Device-Specific Requirements Entitled to Preemptive Effect Outside of a Counterpart Regulation is a Pure Question of Law.**

Similarly, whether 510(k) review itself can “ever” bear preemptive power is a “purely legal question.” *Flores*, 2015 WL 4463639, at \*2. This question requires interpretation of the current statutory and regulatory framework of 510(k) review within the context of the Supreme Court’s preemption jurisprudence, not the parties’ factual circumstances. Therefore, “this prong is satisfied because at least one ‘pure’ question of law is presented.” *Id.* at \*3.

**II. Substantial Grounds for Difference of Opinion Do Exist.**

“A substantial ground for difference of opinion exists . . . when novel legal issues are presented[] on which fair-minded jurists might reach contradictory conclusions,” even

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safety or effectiveness of a non-FDA-approved medical device.”); *McNellis v. Pfizer, Inc.*, No. Civ. 05-1286, 2006 WL 2819046 (D.N.J. Sept. 29, 2006) (certifying order denying summary judgment argument that plaintiffs’ state law claims were preempted by FDCA); *Drake v. Laboratory Corp. of America Holdings*, 290 F. Supp. 2d 352 (E.D.N.Y. 2003) (certifying issue whether drug testing regulations preempted common law tort claims).

1 if “there are no cases directly conflicting with the district court’s construction of the law.”  
 2 *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011). Contrary to Plaintiffs’  
 3 contention, the Ninth Circuit’s “interlocutory appellate jurisdiction does not turn on a  
 4 prior court’s having reached a conclusion adverse to that from which appellants seek  
 5 relief.” *Id.* Plaintiffs ignore this authority in favor of citing out of circuit authority that  
 6 directly conflicts with *Reese*. (See Pl. Resp. at 6 (citing *White v. Nix*, 43 F.3d 374, 378  
 7 (8th Cir. 1994)).)

8 As Bard explained in its Motion, the Ninth Circuit’s opinions in *Degelmann* and  
 9 *Papike*, as well as Justice Gorsuch’s comments regarding the “considerable ‘uncertainty’”  
 10 in the controlling law on FDCA preemption—rules which may “warrant revisiting and  
 11 reconciliation”—demonstrate that fair-minded jurists might reach contradictory  
 12 conclusions on these novel legal issues. *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335,  
 13 1337, 1340 (10th Cir. 2015); *Degelmann v. Advanced Med. Optics, Inc.*, 659 F.3d 835,  
 14 841-42 (9th Cir. 2011) (FDA Guidance can be preemptive), *vacated*, 699 F.3d 1103 (9th  
 15 Cir. 2012); *Papike v. Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997) (device-specific  
 16 regulation preemptive). Therefore, substantial grounds for difference of opinion do exist.  
 17 *Reese*, 643 F.3d at 688.

### 18 **III. Immediate Appeal Will Materially Advance This Litigation.**

19 All that must be shown to satisfy § 1292(b) is that an immediate appeal, *if*  
 20 *successful*, “may materially advance the ultimate termination of the litigation.” 28 U.S.C.  
 21 § 1292(b) (emphasis added); *Brown*, 2012 WL 4364588, at \*3 (“[C]ertification is  
 22 appropriate where a successful appeal would materially advance, though not completely  
 23 dispose of, the litigation.”). Bard made this showing in its opening Motion. Plaintiffs’  
 24 Response does not contradict that showing. Instead, Plaintiffs appear to import additional  
 25 requirements into this criterion of § 1292(b) suggesting that Bard must show: (a) that the  
 26 Ninth Circuit will accept its petition, (b) that Bard *will succeed* on appeal, and (b) that the  
 27 litigation “would [] be terminated.” (Pl. Resp. at 8-9.) Plaintiffs’ position is not supported  
 28 by the law. See *In re City of San Bernardino, California*, 260 F. Supp. 3d 1216 (C.D. Cal.

2013) (rejecting contention that the movant “must prove ‘that resolution of a controlling legal question *would* serve to avoid a trial or otherwise substantially shorten the litigation’” as “an incorrect statement of the law”); *Reese*, 643 F.3d at 688 (litigation sufficiently likely to be materially advanced where the Ninth Circuit’s “possible reversal” “may” remove one defendant and eliminate a set of claims against remaining defendants).

An appeal “must only possess the possibility of materially advancing the litigation.” *Shell Gulf of Mexico, Inc v. Ctr. for Biological Diversity, Inc.*, No. 3:12-CV-0096-RRB, 2012 WL 12871660, at \*2 (D. Alaska Sept. 13, 2012). “In determining such possibility, ‘the court should consider the effect of a reversal by the court of appeals on the management of the case.’” *Id.* (granting certification after finding that “if the Ninth Circuit finds any of this Court’s conclusions to be erroneous, the current litigation would end immediately, with all of the Defendants and all of the claims being removed from the case. Additionally, in ending the current litigation, any further expensive or protracted litigation could be avoided.”); *see also Brown*, 2012 WL 4364588, at \*3 (granting certification of federal preemption issue after finding that if court’s preemption “order were reversed on appeal, it would limit the legal theories under which Plaintiffs could prove their case.”). Bard has shown in its Motion how a reversal of the Summary Judgment Order would materially advance the ultimate termination of the litigation.

Furthermore, Plaintiffs do not address, and therefore concede, that “certification is particularly appropriate in the context of MDL proceedings.” *In re Cintas Corp. Overtime Pay Arbitration Litig.*, No. M06-CV-01781-SBA, 2007 WL 1302496, at \*2 (N.D. Cal. May 2, 2007). Indeed, it is the “favored MDL” practice to certify dispositive rulings for immediate appeal, *id.*, to avoid “the sort of piecemeal litigation that the multidistrict litigation scheme was intended to discourage.” *In re Food Lion, Inc., Fair Labor Standards Act Effective Scheduling Litig.*, 73 F.3d 528, 532 (4th Cir. 1996) (“[P]ermitting the transferor courts (and, possibly, the Courts of Appeal[]) to reconsider the transferee court’s summary judgment orders will frustrate the aims of § 1407. The overriding purpose of the multidistrict procedure dictates that these claims be decided in the same



appellate forum.”); *In re Microsoft Corp. Antitrust Litig.*, 274 F. Supp. 2d 741, 743 (D. Md. 2003) (granting certification; finding it especially “relevant that this is an MDL proceeding”); *see also Lovett v. Omni Hotels Mgmt. Corp.*, No. 14-CV-02844-RS, 2016 WL 7732622, at \*3 (N.D. Cal. Apr. 18, 2016) (certification inappropriate in relatively simple tort dispute as opposed to “a large, multi-district litigation, where immediate resolution of a legal issue will streamline protracted litigation.”).

Therefore, the Order satisfies all prerequisites for certification under 28 U.S.C. § 1292(b), and is especially appropriate here in the context of this MDL.

#### IV. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard’s Motion.

Respectfully submitted this 18th day of December, 2017.

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 18, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.  
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